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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,875	02/01/2007	Patrick Lewis Blott	P08897US00/MP	6850

20995 7590 05/23/2008  
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EXAMINER
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TREYGER, ILYA Y

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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05/23/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/575,875	<b>Applicant(s)</b> BLOTT ET AL.	
	<b>Examiner</b> ILYA Y. TREYGER	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/01/2007; 04/17/2006</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 1-10 of the US Patent Application No. 10/575,875 filed 02/01/2007 are presented for examination.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 5, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanbeck (WO 84/01904).

3. In Re claim 1, Swanbeck discloses a device for rinsing and treating wounds comprising:

a suction cup 10 (Fig. 1) which is the wound dressing made of rubber or plastic (p. 2, ln. 33) and consequently fully capable of forming a fluid-tight seal or closure over a wound; the feed and discharge tubes (inlet and outlet pipes) A and B (Fig. 1) connected to outlet and discharge tubes 11 and 12 (p. 2, ln. 34, 35; Fig. 1); a sterilizing filter (fluid cleansing means) 14 (p. 3, ln. 33; Fig. 1) having an inlet port C (Fig. 1) connected to a fluid offtake tube 12 (Fig. 1) and an outlet port D (Fig. 1) connected to a fluid recirculation tube E (Fig. 1); a fluid reservoir 15 (Fig. 1); a peristaltic pump 13 (p. 2, ln. 37 – p. 4, ln. 1; Fig. 1) which is a device for moving fluid through the wound dressing and cleansing means; an apparatus for supplying thermal energy (p. 4, ln. 3-5).

Applicant claims that the apparatus comprises “optionally” a means for flow switching

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and “optionally a means for bleeding the flowpath. Such limitations do not require that a prior art apparatus comprise the flow switching or bleeding means. With regard to the flow switcher, Swanbeck illustrates tube 11 as separate from the tube that actually enters the fluid within the reservoir. It is the position of the Examiner that this illustration indicates that the tube may be disconnected and connected to a separate supply line. With regard to the bleeding means, it is the position of the Examiner that fluid is supplied via tube 11 from the reservoir 15 and recirculated through the device via tube 12, recirculating the fluid through the flow path.

With regard to applicant’s “means for supplying thermal energy” of claims 2-5, the “means for fluid cleansing” of claims 6-8, the language appears to be an attempt to invoke 35 USC 112, 6<sup>th</sup> paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase “means for ” or “step for; ”
- (B) the “means for ” or “step for ” must be modified by functional language;  
and
- (C) the phrase “means for ” or “step for ” must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant met the limitations set forth in MPEP § 2181, since applicant defines the structure of the “means for” within the claim.

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4. In Re claim 2, Swanbeck discloses the apparatus comprising a thermostatically regulated water bath (p. 4, ln. 4,5) which is an corresponds to the heater claimed by applicant.

5. In Re claim 3, Swanbeck discloses the apparatus comprising thermostatically regulated water bath (p. 4, ln. 4,5) fully capable to be heated by the radiative heater, and therefore the reference discloses the equivalent of the radiative heater.

6. In Re claim 4, Swanbeck discloses the apparatus comprising the thermostatically regulated water bath (p. 4, ln. 4,5), which is conductively heated component of the apparatus flow path in direct conductive contact with the irrigant and/or wound exudates, and therefore is an equivalent of the conductively heated component

7. In Re claim 5, Swanbeck discloses the apparatus comprising a sterilizing filter 14 (p. 3, ln. 33; Fig. 1) which is an equivalent of a single-phase cleansing system.

8. In Re claim 9, Swanbeck discloses the suction cup 10 (Fig. 1) which is the wound dressing made of rubber or plastic, which is a backing layer (p. 2, ln. 33) and consequently fully capable of forming a fluid-tight seal or closure over a wound; inlet pipe A (Fig. 1) for connection to a fluid supply tube 11 (Fig. 1), which passes through and/or under the wound-facing face, outlet pipe B (Fig. 1) for connection to a fluid offtake tube 12 (Fig. 1), which passes through and/or under the wound-facing face, the points F and G (Fig. 1) at which the or each inlet pipi and the or each outlet pipe passes through and/or under the wound-facing face forming a fluid-tight seal or closure over the wound.

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9. In Re claim 10, Swanbeck discloses the method of treating wounds to promote wound healing using the apparatus for aspirating, irrigating and/or cleansing wounds (p. 2, ln. 32 – p. 4, ln. 12; Fig. 1).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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13. Claims 6-8 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Swanbeck (WO 84/01904) in view of Burbank et al. (WO 00/50143). In Re claim 6, Swanbeck discloses the claimed invention discussed above, but does not expressly disclose the apparatus comprising means for fluid cleansing that is a two-phase system, in which the circulating fluid from the wound passes through the means for fluid cleansing and materials deleterious to wound healing are removed, by the circulating fluid coming into direct or indirect contact with another fluid in the means for fluid cleansing.

Burbank teaches the apparatus for peritoneal dialysis which is fully capable of performing cleansing functions for wound healing (See Abstract, ln. 1-7) which is a two-phase system in which the circulating fluid from the wound or body cavity passes through a means for fluid cleansing and materials deleterious to treatment healing are removed by contacting the spent fluid with a regeneration solution, which comprises another fluid. Therefore the reference discloses the equivalent of the means for fluid cleansing as claimed.

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of a treatment apparatus that uses a secondary regeneration or treatment solution to clean or regenerate fluid removed from the treatment area. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the apparatus of Burbank to the wound treatment device of Swanbeck in order

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to provide device with the cleansing apparatus that is known in the art, as demonstrated by Burbank, to be suitable to treat a patient with cleaned recirculated fluid.

14. In Re claims 7 and 8, Swanbeck discloses the wound treatment apparatus discussed above, but does not expressly disclose the device comprising the means for fluid cleansing wherein the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is selectively permeable or not selectively permeable to materials deleterious to wound healing.

Burbank teaches the apparatus for peritoneal dialysis which is fully capable of performing cleansing functions for wound healing comprising the means for fluid cleansing wherein the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is selectively permeable or not selectively permeable to materials deleterious to wound healing (See Abstract, In. 1-7; P. 18, In. 4-7).

The reference discloses the equivalent of the means for fluid cleansing as claimed in claims 7 and 8. The rationale of obviousness rejection discussed above in claim 6 is incorporated herein in its entirety.

### ***Double Patenting***

15. Claim 1 of this application conflict with claim 1 of Application No. 10/576,263. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during



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pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No.

10/576,263. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

18. Claim 1 recites “a conformable wound dressing”; “a backing layer”, “an inlet pipe”, “an outlet pipe”, “a means for fluid cleansing”, “a fluid reservoir”, “a device for moving fluid through the wound”, and “the means for supplying thermal energy”.

It is clear that all the elements of claim 1 are to be found in claim 1 of the '263. The difference between claim 1 of the application and claim 1 of the '263 lies in the fact that the '363 claim includes more elements and is thus much more specific.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,954,680 disclose the NEAR HYPERTHERMIC HEATER WOUND COVERING. US 5,636,643 disclose the WOUND TREATMENT EMPLOYING REDUCED PRESSURE. US 6,800,074 disclose the WOUND TREATMENT APPARATUS. US 4,979,944 disclose the SURGICAL VACUUM EVACUATION DEVICE. US 5,009,635 disclose the PUMP APPARATUS.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ilya Treyger  
Examiner  
AU 3761

//Leslie R. Deak//  
Primary Examiner, Art Unit 3761  
6 May 2008